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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,184	10/18/2001	Michael A. Pellico	45191/WPC/D279	4838

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EXAMINER

ROSE, SHEP K

ART UNIT PAPER NUMBER

1614

DATE MAILED: 12/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10 045184

Applicant(s)

PELLICO

Examiner

SHEP ROSE

Group Art Unit

1614

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 10/6 is/are pending in the application.
Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 10/6 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

This application, Serial No. 10/045,184, was filed on October 18, 2001, by Michael Pellico, with sixteen claims presented, fifteen of which are dependent on claim 1 which recites a two component dental bleaching system with, as a first component, both carbamide peroxide and hydrogen peroxide are in a dental peroxide gel, and as a second component, a base, to increase pH, is included in as an activator gel.

This application is a C/I/P of (A) application Serial No. 09/659,483, filed Sept 11, 2000 with no disclosure of any base in the second component "activator gel", which claims benefit of (B) 60/153162, filed Sept 9, 1999, with no disclosure of any base in the second component "activator gel", and which has been published, as Discus Dental (Pellico) WO/01/17481, on 15 March 2001; (the "activator gels" of (A)(B) with no base in their activator gels", correspond to activator Gels 1 to 12 set forth herein on pages 10 to 15).

The enabled examples herein of activator gels with a base (potassium hydroxide) are set forth herein on pages 16 and 17 activator gels 13, 14, 15, and 16.

Mixtures of these two peroxides were conventional in the prior dental bleaching art, as of applicant; effective October 18, 2001 filing date.

Dependent claims 2, 11 to 16 recite further components that were well known and conventional in dental bleaching systems as of applicant's effective October 18, 2001 filing date, namely:

Claim 2 hydroxypropyl cellulose in the first component dental peroxide gel;

Claim 11, sodium fluoride and potassium nitrate (in the second activator gel), with the base.

Claim 12, potassium nitrate and tetrapotassium pyrophosphate (in the second activator gel) with the base.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 14, 15, 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13, 14, 15, 16 contain the trademark/trade name "KLUCEL GF" "CAB .O. SIL EH .5". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe hydroxypropylcellulose, and fumed silica, respectively and, accordingly, the identification/description is indefinite.

Claims 13, 14, 15 and 16 are drawn to multi-component 9 or 10 conventional and well known excipients for dental peroxide bleaching systems, namely propylene glycol, glycerin, water, peppermint, potassium hydroxide, sodium fluoride, potassium nitrate, and seen also to improperly recite proprietary trade names or trade marks "KLUCEL

GF", "CAB-O.SILEH-5", "ART. CHERRY CH-0556" and "Natural peppermint Oil PE-05523" the precise identify and source of each of which is not disclosed, and is requested for the record but are seen to be conventional dental bleaching system excipients.

CAB.O.SIL is the Registered Trademark of Cabot corporation for Fumed Silicon dioxide as a Suspending and Thickening. Agent, T.M. Reg. No. 581369 and Free-Flowing and anti laking agent, T.M. Reg. No. 721169.

KLUCEL is the Registered Trademark of Hercules Powder Co. for a cellulose ether, T.M. Reg. No. 760,881

The conventional nature of each of these above noted features, each old in the dental bleaching art, raise an issue of obviousness type double patenting of the presented claims in view of claims 1 to 4 of Pellico U.S. 5928628 which differs from these claims in the feature of including carbamide peroxide with the hydrogen peroxide and also with each of the other above noted conventional components of dental peroxide bleaching systems.

Claims 1, 3 to 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 4 of U.S. Patent No. 5,928,628 in view of Montgomery U.S. 6.312.670, claims 1 and 6, wherein carbamide peroxide is kept apart from a base (alkaline or pH adjusting hydroxide) in a two part dental bleaching system (as in "DAY WHITE") and the known prior art description of the mixture of hydrogen peroxide with carbamide peroxide, motivating its inclusion, in.

Jensen et al U.S. 5,858,332 (Jan. 10, 1997) a mixture of hydrogen peroxide solution and carbamide peroxide (col. 5 lines 55-68) (neutralizing (base) hydroxides at col. 6, lines 35 to 50);

Cumulative thereto:

Jensen et al U.S. 6,368,576, claim 13, (to Nov. 12, 1998); (mixture of hydrogen peroxide and carbamide peroxide);

Montgomery et al U.S. 6,343,933, column 8, 63 to 65: hydrogen peroxide, carbamide peroxide, claims 6, 15, 29, combinations of peroxides: (to Feb. 19, 1998);

Jensen et al, U.S. 6,312,671, claims 16, 28 (at least 10% of mixture of carbamide peroxide and aqueous hydrogen peroxide (Dec. 20, 1999);

Oxman et al U.S. 6,312,666, claim 5 (mixture of hydrogen peroxide and carbamide^{peroxide}) (Nov. 12, 1998);

Jensen et al U.S. 6,309,625, claims 25, (mixture of aqueous hydrogen peroxide and carbamide peroxide); (Nov. 12, 1998);

Jensen et al U.S. 6,306,370, claim 10) mixture of hydrogen peroxide and carbamide peroxide) (Nov. 12, 1998);

Ryles et al U.S. 6,280,708, claim 2 (combinations of hydrogen peroxide and urea peroxide (carbamide peroxide) (Sept. 23, 1999);

Montgomery et al. U.S. 6,162,055, (claim 8), combinations of peroxides, column 8, and line 60: hydrogen peroxide, carbamide peroxide (Feb. 19, 1998).

In view of motivation from any of the foregoing, it would be obvious to add carbamide peroxide to the hydrogen peroxide with optimum amounts of each as taught

by Jensen et al U.S. 5,858,332 in first component dental peroxide gel of Pellico U.S. 5,928,628, claims 1 to 4.

Ostler U.S. 6,116,900 (to November 17, 1997) also describes the basic element kept apart from a peroxide chamber to energize (activate) it upon mixing (as in *Day White*) claim 3 has both peroxides.

Claims 2 and 11 to 16 are generic to a plurality of disclosed patentably distinct species comprising

One ultimate disclosed species of:

- (a) hydroxypropylcellulose in the first component dental peroxide gel (claim 2).
- (b) sodium fluoride and potassium nitrate in the second component activator gel with the base (claim 11);
- (c) potassium nitrate and tetrapotassium pyrophosphate in the second component activator gel with the base (claim 12);
- (d) (If further elected), the multi-component activator gel of claim 13;
- (e) (If further elected), the multi-component activator gel of claim 14;
- (f) (If further elected), the multi-component activator gel of claim 15;
- (g) (If further elected), the multi-component activator gel of claim 16;
- (h) (If further elected), a first component percentage of each of carbamide peroxide and of hydrogen peroxide, as in claims, 6, 7, 8, 9 or 10.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species, of each even though this requirement is traversed. If this application is filed under Rule

371, the legal authority is PCT Rule 13.2, Annex B, Part 1 (f) "Markush Practice"; PCT Rule 13 and 35

U.S.C. § 372, rather than 35 U.S.C. § 121.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under U.S.C. § 103 (of) the other invention.

Election of species is required per MPEP § 803, 809.02 (d) (Markush group claim practice, separate and burdensome fields of search required).

Patentably distinct Markush species are independent inventions, In re Webber, 198 USPQ 328, In re Haas, 198 USPQ 334. Divisional applications may be filed under 35 U.S.C. § 121, as a result of an Office requirement for an election of a patentably distinct species as made herein. In re Joyce, 115 USPQ 412, In re Herrick, 115 USPQ 412. This satisfies the "patentably distinct" criterion since the Examiner is not of the opinion that the various species are obviously unpatentable over one another, and each species (as noted above) is capable of independent manufacture, use and sale, with the other components of the claimed formulations.

Applicant is further required to identify the claims that correspond to the elections as well as those that do not even if the requirements are traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is (703) 308-4609. The examiner can normally be reached on Monday, Tuesday and Thursday from 7:30 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Shep Rose
SHEP K. ROSE
PRIMARY EXAMINER

Rose/LR
December 20, 2002